The Human Subjects Institutional Review Board Workshop

Part 1: An Introduction to Human Subjects Research Ethics and the IRB Process

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IRB Who?
Meet the team

- IRB coordinator
  - Screens and assigns proposals
- 10-15 committee members
  - Mostly faculty volunteers
  - Number and composition must reflect capacity for ethics review in different disciplines
- AVP of Office of Research
  - Institutional officer – final approval
IRB Why?
The pieces of the policy puzzle and balancing the ethics scale

Belmont Report
- Respect for persons (informed consent)
- Beneficence (risk/benefit analysis)
- Justice (equitable subject selection)

Federal Regulations (45 CFR 46)

SJSU Policy for the Protection of Human Subjects (S08-7)

The IRB protocol/proposal
IRB What & When?
A different process for different work

**Before** commencement of work!!

- Exclusion (2-5 business days)
- Exemption (7-10 business days)
- Expedited Review (one month)
- Full Review (one month or more - no summer and winter schedule)
- Registration (2-5 business days)
Exclusion (Notification time: 2-5 business days)

The (only) two criteria for review

❖ Is your work research?
  • A **systematic investigation** designed to contribute to **generalizable knowledge**
  • Usually includes a publication/dissemination component

❖ Does your work involve human subjects?
  • Direct interaction / intervention with individuals
  • Analysis of or access to private records
Exemption (Notification time: 7-10 business days)

Oversight without a formal IRB review

- Research that’s no greater than minimal risk
- No protected groups – children, pregnant women, prisoners...
- Must fit into at least one of the prescribed categories
  (see exemption screening form)
- Office of Research screens for eligibility and registers the research
- Complete protocol required
Formal (non-exempt) IRB Review Categories
(Notification of approval time: 1 month)
“Expedited” is defined by how well prepared your protocol is

**Expedited Review**
- **Default** review process if research is not eligible for exemption
- One reviewer evaluates and approves the protocol

**Full Review**
- IRB member optional recommendation
- A majority of committee members must decide
- Problematic protocols/ethical concerns
IRB Registration (Notification time: 2-5 business days)

One form for (almost) everything else

Express your intent to conduct human subjects research if you are:

- An SJSU investigator with a pending grant
- An SJSU investigator with IRB approval from an outside institution
- An outside investigator with IRB approval from home institution

No review takes place!

Creates a paper trail for documenting compliance
Addendums and Extensions
(Notification of approval time: 7-10 business days)
Investigator responsibilities after IRB approval

• Communicate any significant changes to IRB coordinator via email - always include your tracking number
• Approval is granted for one year
• Investigators must apply for an extension to continue with data collection beyond the one year approval period
• Use Extension Request Form
• Report any problems or injuries immediately to the Office of Research
IRB How?
As in, “How long is this going to take? I needed approval yesterday!”

Possible reasons for delay:
• Not enough info from investigator/missing documents/conflicting info within protocol
• Protected groups
• Adversarial relationship between investigator and IRB
• Human error
IRB Process Flow Chart (can only occur prior to initiation of research)

IRB Coordinator

IRB Review:
- Complete Protocol Required
  - Expedited (one reviewer)
  - Full (all reviewers)

  Revisions or resubmits as requested by IRB

  AVP Pam Stacks grants final approval

  PI is notified of approval; valid for 1 year from approval date

Exempt Registration:
- Complete Protocol Required
  - IRB coordinator

  Revisions or resubmits as requested by IRB coordinator

  AVP Pam Stacks grants final approval

  PI is notified of approval; valid for 1 year from approval date

Extensions and Addendums to Approved IRB Protocol:
- IRB coordinator or IRB Reviewer

  Revisions or resubmits as requested by IRB coordinator or IRB Reviewer

  AVP Pam Stacks grants final approval

  PI is notified of approval; valid for 1 year from approval date

Registration (acknowledgement that documents were received):
- IRB coordinator

  • Pending grant. Submit Intent to Conduct Human Subjects Research Form. Standard screening for IRB review or exemption takes place once PI submits a complete IRB protocol. SJSU approval required prior to initiation of research.

  • IRB approval obtained from outside institution for involvement of SJSU investigator. Submit a copy of the IRB approval, a complete copy of the approved protocol, and the Intent to Conduct Human Subjects Research Form. SJSU IRB approval not required.

  • IRB approval obtained from outside institution for outside investigator conducting research at SJSU. Submit a copy of the IRB approval, a complete copy of the approved protocol, and the Intent to Conduct Human Subjects Research Form. SJSU IRB approval not required.

Notifications of registration are issued by the IRB coordinator; such notifications are not an indication that the protocol has been reviewed or approved by the SJSU IRB or that the protocol qualifies for exemption.
IRB How?
As in, “How do I get the ball rolling?”

Utilize the many resources available:

- [IRB website](http://www.sjsu.edu/research/irb)
- [IRB checklist](#)
- [IRB FAQs](#)
- [IRB workshop](#) (student and discipline centered)
- [CITI training](#)
- Contact the IRB coordinator...
IRB Questions?

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Don’t forget to view Part 2 of this IRB Workshop...

Preparing Your IRB Protocol